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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,865	11/18/2005	Duncan Robert Keeble	78104093-N17081	5787

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Intellectual Property Department
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EXAMINER	
ROGERS, DAVID A	

ART UNIT	PAPER NUMBER
2856	

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/538,865	KEEBLE, DUNCAN ROBERT	
	Examiner	Art Unit	
	David A. Rogers	2856	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-35,38-41 and 43* is/are rejected.

7)☒ Claim(s) *36,37 and 42* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 June 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/14/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

The specification must be amended to include a method and apparatus for testing using a resilient outer sheath in addition to an inner tube as seen in claims 36, 37, and 42.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the embodiment having both an inner tube and an outer sheath, as found in claims 36, 37, and 42, must be shown (preferably as a new figure showing this second embodiment) or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes

made to the brief description of the several views of the drawings for consistency.

Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claim 25 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 23 requires an insert that has a cavity that is expanded and contracted by increasing and decreasing the pressure in the cavity. This would inherently require providing fluid under pressure as in claim 25.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 22-28, 31, 33, 35, 38-40, and 43 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by United States Patent 5,792,603 to Dunkelman *et al.*

Dunkelman *et al.* discloses a method and apparatus for testing vascular implants (reference item 26). As seen in figure 1 the vascular implant (reference item 26) is located in a testing chamber (reference item 14). The testing utilizes a resilient insert (reference item 32) that has been inserted within the vascular implant. An alternating pressure source (reference item 16) is used to cause the vascular implant to repeatedly expand and contract.

With regard to claims 23, 25, 27, and 39 the insert inherently has an internal cavity. The alternating pressure source is used to repeatedly increase and decrease the pressure inside the insert. The tube in figure 1 would be closed at one end in order to allow the tube to be pressurized.

With regard to claim 24 Dunkelman *et al.* discloses that the resilient tube can be formed from an angioplasty balloon. Official notice is hereby taken that angioplasty balloons are known to have a wall thickness of between 0.03mm to 0.20 mm.

With regard to claim 27 Dunkelman *et al.* discloses:

> "It is to be understood that *during testing*, seeding, and culturing in a preferred embodiment, the fluid may be advantageously kept at human body temperature, and may be composed of a fluid which approximates the viscosity of human blood. *One illustrative example of a solution which approximates the viscosity of blood is saline with glycerol*."

Clearly Dunkelman *et al.* discloses the use of a saline solution for testing.

With regard to claim 28 the tube is disclosed as being formed of "any suitable elastomeric material" including PET (polyethylene terephthalate) and silicone angioplasty balloons.

With regard to claim 31 the apparatus of Dunkelman *et al.* further comprises a fluid reservoir (reference item 10) and a pump (reference item 12) that can pump saline solution through the chamber via an inlet (reference item 28) and an outlet (reference item 30). The apparatus does not comprise a mean to purge the chamber of the saline solution before testing with the alternating pressure source. The apparatus of Dunkelman *et al.*, therefore, performs testing of the vascular implant while the implant is immersed in the saline solution.

With regard to claim 33 official notice is hereby taken that vascular implants, including those contemplated and tested by Dunkelman *et al.*, are known in the art to have an internal diameter from 2 mm to 50 mm in order that they are useful as vascular implants in humans.

With regard to claim 35 the outer surface of the tube is not directly attached to the inner surface of the vascular implant. Therefore, when pressure in the tube is reduced the tube will contract. Likewise the vascular implant will also contact under its own resilience since testing would not exceed the implant's elastic limit.

6. Claims 22-26, 28, 30, 32, 35, 38, 40, and 43 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by United States Patent 6,810,751 to Moreno *et al.*

Moreno *et al.* discloses a method and apparatus for testing vascular implants (reference item 522). As seen in figure 6 the testing utilizes a resilient insert (reference item 520) that has been inserted within the vascular implant. Figure 6 does not show the testing of a bifurcated vascular implant. However, Moreno *et al.* states:

> "As should be apparent to one skilled in the art, the concept of forming a test member by placing the stent-graft upon the exterior of the fluid conduit is not limited to the testing configuration depicted in FIG. 6, but has wide application, and is suitable for any testing configuration, including but not limited to those depicted in FIGS. 1-4."

Figures 1-4 clearly show the testing of bifurcated vascular implants. Fluid pressure is used to expand the vascular implants. See column 5 (lines 45-58).

With regard to claims 23, 25, and 26 the insert inherently has an internal cavity. The alternating pressure source is used to repeatedly increase and decrease the pressure inside the insert using a saline solution. See column 5 (lines 45-58).

With regard to claims 24 and 28 Moreno *et al.* discloses that the resilient tube can be formed from silicone that has a thickness of about 0.2 mm. See column 4 (lines 17-20).

With regard to claim 29 Moreno *et al.* teaches the testing of vascular implants using a silicone-based tube having a wall thickness of about 0.2 mm. The applicant's specification describes the inner tube as being having very thin walls and formed of latex, silicone, or polyurethane. The wall thickness is

disclosed as being between 0.03 mm to 0.2 mm. Since the tube of Moreno *et al.* has very thin walls (about 0.2 mm) and is made of silicone it meets the structural limitations described as preferred by the applicant and is, therefore, analogous to a "contraceptive condom."

With regard to claims 30 and 40 Moreno *et al.* discloses that testing can be done at 6000 cycles/minute which equals 100 Hz.

With regard to claim 35 the outer surface of the tube is not directly attached to the inner surface of the vascular implant. Therefore, when pressure in the tube is reduced the tube will contract. Likewise the vascular implant will also contact under its own resilience since testing would not exceed the implant's elastic limit.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 30 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunkelman *et al.* as applied to claim 22 above, and further in view of United States Patent 6,881,224 to Kruse *et al.*

Dunkelman *et al.* teaches fatigue testing of a vascular implant using cyclic pressure. Dunkelman *et al.* does not expressly teach a cyclic frequency used during the testing of between 50 Hz to 100 Hz (3000 cycles/min. to 6000 cycles/min.).

Kruse *et al.* teaches cyclic testing of vascular implants. In particular, Kruse *et al.* teaches that the testing can be performed from about 1000 cycles/min. to about 5000 cycles/min. These frequencies allow for accelerated testing of the vascular implant.

Kruse *et al.* also teaches that vascular implant should last for about 400 million to 600 million cycles. See column 10 (lines 35-48). At 1000 or 5000 cycles per minute:

$$\frac{400{,}000{,}000\ cycles}{\left(1000\ {}^{cycles}/_{min.}\right)\left(60\ {}^{min.}/_{hr}\right)\left(24\ {}^{hr}/_{day}\right)\left(7\ {}^{days}/_{week}\right)} = 39.6\ weeks$$

$$\frac{400{,}000{,}000\ cycles}{\left(5000\ {}^{cycles}/_{min.}\right)\left(60\ {}^{min.}/_{hr}\right)\left(24\ {}^{hr}/_{day}\right)\left(7\ {}^{days}/_{week}\right)} = 7.94\ weeks$$

Therefore, one can quickly observe that testing must occur for greater than 7 weeks in order to reach the minimum of 400 million test cycles.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Dunkleman *et al.* with the teachings of Kruse *et al.* in order test the vascular implant at a frequency of between 50 Hz to 100 Hz in order to accelerate the testing; i.e., reduce the amount of time testing the vascular implants.

9. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moreno *et al.* as applied to claim 38 above, and further in view of United States Patent 5,327,774 to Nguyen *et al.*

Moreno *et al.* teaches the use of a diaphragm pump for increasing the pressure within a vascular implant during the testing of the implant. Moreno *et al.* does not expressly teach the use of air as the means for pressurizing.

Nguyen *et al.* also teaches that it is known in the art to use diaphragm pumps to test vascular implants. Nguyen *et al.* also teaches that the diaphragm pumps can be operated using air as the pressurizing means.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Moreno *et al.* with the teachings of Nguyen *et al.* in order to use air-based diaphragm pumps as the pressurizing means for testing vascular implants. As taught by Nguyen *et al.* the air-based diaphragm pumps can provide flow that simulates those that occur physiologically in humans. See column 6 (lines 17-40).

Allowable Subject Matter

10. Claims 36, 37, and 42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Rogers whose telephone number is (571) 272-2205. The examiner can normally be reached on Monday - Friday (0730 - 1600). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron E. Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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05 September 2006

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